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PATREA L PABST  
HOLLAND & KNIGHT LLP  
ONE ATLANTIC CENTER  
1201 WEST PEACHTREE STREET, SUITE 2000  
ATLANTA GA 30309-3400

EXAMINER

SMITH, R

ART UNIT

PAPER NUMBER

3737

12

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/229,226

Applicant(s)

LIU ET AL.

Examiner

Ruth S Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-31 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Claim Rejections - 35 USC § 112***

Claims 9,17,19,20,22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9,17 are vague and indefinite in that it is unclear as to what further step in the method has been set forth. It appears that such limitations are inherent results of the method. With regard to claim 17, it is unclear as to what conditions is the acoustic energy applied under other than those set forth in claim 1 in order to effect cavitation. Claims 19, 20 are vague and indefinite if the property that is measured is other than the frequency.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5,7,14,15,18,23,25,26 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al. The claims are directly readable on Tachibana et al which disclose the use of ultrasound to alter cell viability. The ultrasound is administered for a predetermined time period after which it is terminated. The intensity was varied over time and the ultrasound was used to kill cells. The ultrasound was applied at a frequency of 270 KHz and used with agent such as Photofrin II. Figure 1 shows the device used to carry out the method. Tachibana et al discloses that the ultrasound is administered for set time periods. Therefore, the method inherently includes a step of monitoring the time period that the ultrasound is applied and stopping its application at a predetermined time.

Art Unit: 3737

Claims 27-28,30,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Eppstein et al. The claims are directly readable on Eppstein et al which disclose the use of ultrasound energy to alter transport of agents into the body. The frequency can be changed such that the energy is directed to a deeper part of the tissue. Therefore, the energy is administered at the skin by a transducer placed thereon and the energy alters transport and cell viability at a site distant from the layer of skin on which the transducer is placed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,8-18,23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bommannan. Bommannan et al disclose administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The energy is administered for a time period which can be selected based upon the drug administered, and the disease or injury treated (see column 7, lines 6-10). The measurement of the time that the ultrasound is applied is a measurement of a

Art Unit: 3737

property of the acoustic energy. It would have been obvious to one skilled in the art to have monitored the treatment time and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient. The agent passed through the membrane can be peptides or proteins and in the form of an emulsion. Bommannan et al further disclose that the method can be used to sample and evaluate biological fluids in the body (see column 4, lines 55-59). With regard to claim 9, it appears that such is an inherent function of the method. With regard to claim 13, it appears that the method of Bommannan et al would be applicable to any type of biological membrane. With regard to claim 14, Bommannan et al disclose a frequency above about 10MHz. In the absence of any showing of criticality, it would have been obvious to one skilled in the art to have used to frequency set forth by Bommannan et al in that such is a difference in degree rather than kind from the frequency set forth in the claim. It should be noted that applicant discloses frequencies in the range of up to 100 MHz can be used. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 17, the step is an inherent result of the method. With regard to claims 23,24, the total exposure time and device location can be changed depending upon the procedure being performed.

Claims 1-5,8-18,23-26,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein et al. Eppstein et al disclose administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The frequency and/or intensity can be selected based upon the drug administered, and the disease or injury treated. It would have been obvious to one skilled in the art to have monitored the treatment time and intensity/frequency used and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient. With respect to claim 3, the agent passed through the membrane would have been an obvious selection based upon the intended treatment, and in the form of an

Art Unit: 3737

emulsion or liposome as is well known. With regard to claim 9, it appears that such is an inherent function of the method. With regard to claims 13,29, it appears that the method of Eppstein et al would be applicable to any type of biological membrane and to any type of cell. With regard to claim 14, Eppstein et al disclose a frequency in the range of .1-100MHz. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 17, the step is an inherent result of the method. With regard to claims 23,24, the frequency and device location can be changed depending upon the procedure being performed.

Claims 1-5,8-18,23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden. Ogden discloses administering acoustic energy to skin or other biological membrane in order to alter the permeability of the membrane. The frequency and/or intensity can be selected based upon the drug administered, and the disease or injury treated. Ogden discloses that the frequency and treatment time can be changed. A feedback loop is used to monitor drug delivery amounts and temperature and the treatment is affected by such measurements. The agents and enhancers set forth in the claims are disclosed in column 5. It would have been obvious to one skilled in the art to have monitored the treatment time and intensity/frequency used and end treatment after the desired time has passed in order to avoid transmitting excessive waves through the patient as set forth in column 6. With regard to claim 13, it appears that the method of Ogden would be applicable to any type of biological membrane and to any type of cell. With respect to claim 16, in the absence of any showing of criticality, the peak positive pressure used would have been obvious to one skilled in the art without undue experimentation in order to achieve the desired result. With regard to claim 24, the frequency and device location can be changed depending upon the procedure being performed.

***Allowable Subject Matter***

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19,20,22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 8/8/01 have been fully considered but they are not persuasive. Eppstein et al discloses that the delivery of the drug through the skin is to an internal tissue. Therefore, the claims still read on Eppstein et al. Applicant has not provided an argument regarding the rejection under 35 USC 103 with respect to Eppstein et al.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3737

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is 308-3063. The examiner can normally be reached on M-F 5:30AM -2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0858.



Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS  
October 18, 2001



**Attachment for PTO-948 (Rev. 03/01, or earlier)**  
**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any). If an application number has not been assigned to the application, if this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL - 37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.